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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,116	DUDEK ET AL.	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-35 and 39-41* is/are pending in the application.

4a) Of the above claim(s) *41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-35,39 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *December 12, 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 25-35 AND 39-41 ARE PRESENTED FOR EXAMINATION

Applicants' "Reply to Restriction Requirement" filed January 28, 2005 has been received and entered into the application. Accordingly, the specification at page 1 (indicating the current status of the related applications) and claims 25-31, 35 and 41 have been amended and claims 1-24 and 36-38 have been canceled.

Numbering of Claims

With regard to re-number of the claims, Applicants have indicated that 37 C.F.R. § 1.126 does not apply, "since 'original' claims 1-24, for example, should have never been entered since they were not part of the substitute specification. Rather claims 1-14 (now renumbered as claims 25-35 and 39-41) should have been entered as the 'original' claims.".

In Applicants' substitute specification, however, an "original" set of claims numbered as 1-24 were, in fact, presented, e.g., at pages 92-103 of the substitute specification. Even though claims 1-24 were in "canceled" form when presented, these claims were nevertheless present and the presentation of these claims establishes the basis for the claim numbering in the present application.

Accordingly, the re-numbering of the non-canceled claims as originally filed under 37 C.F.R. § 1.126 is proper.

Declaration and Support for Claimed Subject Matter

In light of Applicants' remarks at pages 6-7 of the reply referenced above, the Examiner's request for a new declaration and indication of support for the claimed subject matter is withdrawn.

Restriction Requirement

In response to the restriction requirement set forth in the previous Office action, Applicants have stated "Applicants hereby elect, for search purposes only, claim 40, drawn to a 'method for treating or preventing stroke, comprising administering a composition including a cAMP antagonist to a patient,' with traverse." (reply at page 7, second paragraph).

While such is not technically a proper reply, in order to expedite prosecution of the present application, such will be taken to indicate that Applicants elect the invention of Group I for examination, with traverse, i.e., the election of a claim and the election for "search purposes" were not options provided for in the previous Office action (see page 6 under the heading "Election Options" where an election of a group is indicated and page 8, fifth full paragraph where "an election of the invention to be examined" is indicated).

Accordingly, claims 25-34, 35 (to the extent that the regulation of neural tissue encompasses a treatment of stroke), 39 and 40 are herein acted on the merits.

Claim 41 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicants timely traversed the restriction requirement in the reply filed on January 28, 2005, referenced above.

Applicants' traverse of the restriction requirement set forth in the previous Office action has been carefully considered, but fails to persuade the Examiner of error in his determination.

In particular, while Applicants may be of the opinion that a serious burden would not be placed on the Examiner in considering all of grouped inventions, the Examiner maintains his position to the contrary. In particular, that a contemporaneous search for all of the claimed

subject matter in both the patent and non-patent literature and evaluation of such under 35 U.S.C. §§ 101, 102, 103 and/or 112 would impose a serious burden on the Examiner in conducting a full and proper examination of the present application.

Accordingly, for the above reasons, the restriction requirement is deemed proper and is hereby made **FINAL**.

Specification

The specification is objected to because of the term "norepinepurine" at page 48, line 13. This term appears to be a misspelling of the compound "norepinephrine". Clarification and/or correction is required.

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 40 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating stroke, does not reasonably provide enablement for the prevention of the same. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Burden on the Examiner for Making a Rejection Under 35 U.S.C. § 112 First Paragraph

As set forth in *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971):

"[A] [s]pecification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling

requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contain therein which must be relied on for enabling support*; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling." (emphasis added).

Here, the objective truth of the statement that stroke may be prevented is doubted because the art teaches that, at best, the incidence of stroke may be reduced and such is indicative of that the prevention of stroke is merely a possibility and not a treatment outcome that can be accomplished with a reasonable degree of certainty.

Further, the term "preventing" may be reasonably interpreted as being synonymous with the term "curing" and both circumscribe methods of absolute success. Because absolute success is not reasonably possible with most diseases/disorders, especially those having an etiology and pathophysiological manifestations as complex/poorly understood as stroke, the specification, which lacks an objective showing that stroke can actually be prevented, is viewed as lacking an enabling disclosure of the same.

The Examiner notes that the term "prevent" is not *necessarily* synonymous with "cure", but such interpretation is proper given that "During patent examination, the pending claims must be 'given their broadest reasonable interpretation consistent with the specification.' *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969)." (MPEP § 2111) (emphasis added).

As noted above, the basis of the Examiner's doubt lies in that the art teaches that, at best, the incidence of stroke may be reduced and such is indicative of that the prevention of stroke is merely a possibility and not a treatment outcome that can be accomplished with a reasonable degree of certainty. In support thereof, the Lancet reference authored by Wolf, Philip A. (newly cited by the Examiner), is relied on. Therein, while it is stated that "Findings from clinical trials and observational data indicate that stroke can be prevented and the risk of stroke recurrence reduced." (page sIII15, col. 1, middle of the second paragraph), it is clear from the remaining section of the reference, that the author does not intend to indicate that stroke may be kept from ever occurring, but rather that the occurrence or incidence of stroke may be reduced. Thus, the author further states that "Preventive measures [are taken] *to reduce stroke and stroke recurrences*." (emphasis added)(page sIII15, col. 1, middle of the second paragraph); "It is possible that reduction of raised plasma homocysteine and improved control of blood glucose in diabetics may also *reduce stroke incidence* but data are lacking. Prevention and treatment of predisposing cardiac diseases – coronary-heart disease (CHD), congestive heart failure, atrial fibrillation (AF), increased left ventricular mass, and valvular heart disease – will *probably help to reduce stroke occurrence*."(emphasis added) (page sIII15, col. 1, end of second paragraph); and "An overview of 14 treatment trials in 37 000 (sic) hypertensive patients led to the conclusion that an average blood-pressure reduction of 5.8 mm Hg resulted in a 42% *reduction in stroke incidence*."(emphasis added)(page sIII15, sentence bridging cols. 1-2).

Summary

As the cited art and discussion above establish, practicing the claimed method in the manner disclosed by Applicants would not imbue the skilled artisan with a reasonable

expectation that the prevention of stroke could be achieved. In order to actually achieve the prevention of stroke, it is clear from the discussion above that the skilled artisan could not rely on Applicant's disclosure as required by 35 U.S.C. § 112, first paragraph. Given that the art fails to recognize, and Applicants have failed to demonstrate, that stroke could actually be prevented, the skilled artisan would be faced with the impermissible burden of undue experimentation in order to practice this embodiment of the claimed invention. Accordingly, claim 40 is deemed properly rejected.

Overcoming the Above Rejection

The Examiner recommends that Applicants delete "or preventing" in claim 40, line 1 in order to overcome the present rejection.

Legal Standard for Anticipation/Inherency Under - 35 USC § 102

To anticipate a claim under 35 U.S.C. § 102, a single prior art reference must place the invention in the public's possession by disclosing each and every element of the claimed invention in a manner sufficient to enable one skilled in the art to practice the invention. *Scripps Clinic & Research Foundation v. Genetech, Inc.,* 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1001 (Fed. Cir. 1991); *In re Donahue,* 766 F2d531, 533, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985). To anticipate, the prior art must either expressly or inherently disclose every limitation of the claimed invention. *MEHL/Biophile Int'l Corp. v. Milgraum,* 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1303 (Fed. Cir. 1999) (citing to *In re Schreiber,* 128 F.3d 1473, 1477, 44 U.S.P.Q. 1429, 1431 (Fed. Cir. 1997)); *Atlas Powder Co. v. Ireco Inc.,* 190 F.3d 1342, 1347, 51 U.S.P.Q.2d 1943, 1946 (Fed. Cir. 1999). To inherently anticipate, the prior art must necessarily function in accordance with, or include, the claimed limitations. *MEHL/Biophile,* 192 F.3d at

1365, 52 U.S.P.Q.2d at 1303. However, it is not required that those of ordinary skill in the art recognize the inherent characteristics or the function of the prior art. *Id.* Specifically, discovery of the mechanism underlying a known process does not make it patentable.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 25-35, 39 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Hipskind et al. (U.S. Patent No. 5,891,875) who teach a method for treating stroke or cerebral ischemia through the administration to a mammal, e.g., *in vivo,* of an effective amount of a morpholine compound disclosed therein as being tackykinin receptor antagonists (see the abstract, col. 4, line 1 – col. 5, line 10 and col. 51, line 53). The patentees further teach *in vivo* contacting of the compounds with cells wherein inhibition of adenylate cyclase is measured (col. 55, lines 3-10).

The reference fails to expressly disclose the presently claimed physiological/biochemical functions/activities, i.e., present claims 25, 27-31 and 39. However, because the present specification at page 48, line 16, indicates that the compounds of the above cited U.S. Patent are "compounds which may be used to reduce the levels of or activity of cAMP", the Examiner must presume that the compounds of Hipskind et al. are those of the present claims. Therefore, because the reference teaches the same compounds as in the present claims and the same method

steps as required in the present claims, i.e., contacting cells, the claimed physiological/biochemical functions/activities are deemed inherent in the prior art method. "'[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer.' *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). (MPEP § 2112(I)).

This presumption is further deemed proper because the Examiner is not equipped to conduct tests in order to determine the exact activity of the compounds of Hipskind et al. "As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972)." (MPEP § 2113, last sentence).

Accordingly, for the above reasons, the claims are deemed properly rejected and none of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J Henley III
Primary Examiner
Art Unit 1614

March 11, 2005